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APPLICATION NO.	FILING DATE	FIRST NAMED INVENTOR	ATTORNEY DOCKET NO.	CONFIRMATION NO.
10/607,103	06/27/2003	Arieh Levy	25821	3612

7590

06/17/2005

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EXAMINER

ROBINSON, KEITH O NEAL

ART UNIT

PAPER NUMBER

1638

DATE MAILED: 06/17/2005

Please find below and/or attached an Office communication concerning this application or proceeding.

Office Action Summary

Application No.

10/607,103

Applicant(s)

LEVY ET AL.

Examiner

Keith O. Robinson, Ph.D.

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-- The MAILING DATE of this communication appears on the cover sheet with the correspondence address --
Period for Reply

A SHORTENED STATUTORY PERIOD FOR REPLY IS SET TO EXPIRE 3 MONTH(S) FROM THE MAILING DATE OF THIS COMMUNICATION.

- Extensions of time may be available under the provisions of 37 CFR 1.136(a). In no event, however, may a reply be timely filed after SIX (6) MONTHS from the mailing date of this communication.
- If the period for reply specified above is less than thirty (30) days, a reply within the statutory minimum of thirty (30) days will be considered timely.
- If NO period for reply is specified above, the maximum statutory period will apply and will expire SIX (6) MONTHS from the mailing date of this communication.
- Failure to reply within the set or extended period for reply will, by statute, cause the application to become ABANDONED (35 U.S.C. § 133). Any reply received by the Office later than three months after the mailing date of this communication, even if timely filed, may reduce any earned patent term adjustment. See 37 CFR 1.704(b).

Status

- 1) ☒ Responsive to communication(s) filed on 16 March 2005.
2a) ☐ This action is FINAL. 2b) ☒ This action is non-final.
3) ☐ Since this application is in condition for allowance except for formal matters, prosecution as to the merits is closed in accordance with the practice under *Ex parte Quayle*, 1935 C.D. 11, 453 O.G. 213.

Disposition of Claims

- 4) ☒ Claim(s) 1-21 is/are pending in the application.
4a) Of the above claim(s) 16-18 is/are withdrawn from consideration.
5) ☐ Claim(s) _____ is/are allowed.
6) ☒ Claim(s) 1-6, 9-15 and 19-21 is/are rejected.
7) ☒ Claim(s) 7 and 8 is/are objected to.
8) ☐ Claim(s) _____ are subject to restriction and/or election requirement.

Application Papers

- 9) ☐ The specification is objected to by the Examiner.
10) ☐ The drawing(s) filed on _____ is/are: a) ☐ accepted or b) ☐ objected to by the Examiner.
Applicant may not request that any objection to the drawing(s) be held in abeyance. See 37 CFR 1.85(a).
Replacement drawing sheet(s) including the correction is required if the drawing(s) is objected to. See 37 CFR 1.121(d).
11) ☐ The oath or declaration is objected to by the Examiner. Note the attached Office Action or form PTO-152.

Priority under 35 U.S.C. § 119

- 12) ☐ Acknowledgment is made of a claim for foreign priority under 35 U.S.C. § 119(a)-(d) or (f).
a) ☐ All b) ☐ Some * c) ☐ None of:
1. ☐ Certified copies of the priority documents have been received.
2. ☐ Certified copies of the priority documents have been received in Application No. _____.
3. ☐ Copies of the certified copies of the priority documents have been received in this National Stage application from the International Bureau (PCT Rule 17.2(a)).
* See the attached detailed Office action for a list of the certified copies not received.

Attachment(s)

- 1) ☒ Notice of References Cited (PTO-892)
2) ☐ Notice of Draftsperson's Patent Drawing Review (PTO-948)
3) ☐ Information Disclosure Statement(s) (PTO-1449 or PTO/SB/08)
Paper No(s)/Mail Date _____
4) ☐ Interview Summary (PTO-413)
Paper No(s)/Mail Date. _____
5) ☐ Notice of Informal Patent Application (PTO-152)
6) ☐ Other: _____

DETAILED ACTION

1. Applicant's election of Group I (claims 1-15 and 19-21) in the reply filed on March 16, 2005 is acknowledged. Because applicant did not distinctly and specifically point out the supposed errors in the restriction requirement, the election has been treated as an election without traverse (MPEP § 818.03(a)).

Because the Examiner did not find art on cv 1057, the election of species has been withdrawn and claims directed to the nonelected species have also been examined.

2. Claims 16-18 are withdrawn from further consideration pursuant to 37 CFR 1.142(b) as being drawn to a nonelected group, there being no allowable generic or linking claim. Election was made **without** traverse in the reply filed on March 16, 2005.

3. Applicant is reminded that upon the cancellation of claims to a non-elected invention, the inventorship must be amended in compliance with 37 CFR 1.48(b) if one or more of the currently named inventors is no longer an inventor of at least one claim remaining in the application. Any amendment of inventorship must be accompanied by a request under 37 CFR 1.48(b) and by the fee required under 37 CFR 1.17(i).

Claim Objections

4. Claim 11 is objected to because of the following informalities:

(a) Claim 11 is objected for the phrase "capable of expressing". This phrase does not suggest that the plants that are regenerated from the tissue culture will have all the morphological and physiological characteristics of the paprika plant. It is suggested that this phrase be replaced with - - having - -.

Appropriate correction is required.

Claim Rejections - 35 USC § 112, second paragraph

5. The following is a quotation of the second paragraph of 35 U.S.C. 112:

The specification shall conclude with one or more claims particularly pointing out and distinctly claiming the subject matter which the applicant regards as his invention.

6. Claims 19-21 are rejected under 35 U.S.C. 112, second paragraph, as being indefinite for failing to particularly point out and distinctly claim the subject matter which applicant regards as the invention.

Claims 19 and 21 are drawn to a method and system, respectively, of generating or developing a paprika plant using plant breeding techniques which employ a paprika plant, or its parts, as a source of plant breeding material, wherein said method utilizes paprika plant *Capsicum annuum* cv 1056 or *Capsicum annuum* cv 1057 as a source of breeding material.

The claims do not particularly point out how the paprika plant *Capsicum annuum* cv 1056 or *Capsicum annuum* cv 1057 will be "utilized". It cannot be ascertained if the plants will be crossed with other plants (interspecific crosses) or crossed with other C.

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annuum plants (intraspecific), or if the plants will be used as DNA sources for RFLPs, genetic markers, or transformation.

Claim 20 refers to a group of plant breeding techniques and lists "transformation" as one of the techniques. Transformation is not a plant breeding technique; it is a molecular biology technique that may be used in plant breeding.

Claim Rejections - 35 USC § 112, first paragraph

Written Description

7. The following is a quotation of the first paragraph of 35 U.S.C. 112:

The specification shall contain a written description of the invention, and of the manner and process of making and using it, in such full, clear, concise, and exact terms as to enable any person skilled in the art to which it pertains, or with which it is most nearly connected, to make and use the same and shall set forth the best mode contemplated by the inventor of carrying out his invention.

8. Claims 1-6, 9-15 and 21 are rejected under 35 U.S.C. 112, first paragraph, as failing to comply with the written description requirement. The claim(s) contains subject matter which was not described in the specification in such a way as to reasonably convey to one skilled in the relevant art that the inventor(s), at the time the application was filed, had possession of the claimed invention. The claims are drawn to any paprika plant having various characteristics and parts thereof.

The specification does not provide a written description for the genus of paprika plants as is broadly claimed. Though Applicant has limited the dependent claims to specific traits, these traits are not drawn to a specific paprika plant. Thus, the claims are broadly drawn to any paprika plant from the genus of paprika plants that have the

claimed traits. There is written description for only two species of paprika, namely *Capsicum annuum* cv. 1056 and cv. 1057 (see page 10, line 20 to page 14, line 28).

Furthermore, with regard to claim 21, there is no description in the specification of the “a system” for developing a paprika plant using plant breeding techniques. The claims are broadly drawn to any “system” for developing paprika plants. The specification does not describe the broad genus of systems that are available to develop paprika plants. The specification only describes a system comprising the crossing of Lehava with line 4126, the selection and self-fertilization of the resultant F1, and the use of pedigree breeding over the F2 to F6 generations (see page 11, lines 1-8).

The Federal Circuit has recently clarified the application of the written description requirement. The court stated that a written description of an invention “requires a precise definition, such as by structure, formula, [or] chemical name, of the claimed subject matter sufficient to distinguish it from other materials”. *University of California v. Eli Lilly and Co.*, 119 F.3d 1559, 1568; 43 USPQ2d 1398, 1406 (Fed. Cir. 1997). The court also concluded that “naming a type of material generally known to exist, in the absence of knowledge as to what that material consists of, is not description of that material”. *Id.* Further, the court held that to adequately describe a claimed genus, Patent Owner must describe a representative number of the species of the claimed genus, and that one of skill in the art should be able to “visualize or recognize the identity of the members of the genus”. *Id.*

See MPEP Section 2163, page 156 of Chapter 2100 of the August 2001 version, column 2, bottom paragraph, where it is taught that

[T]he claimed invention as a whole may not be adequately described where an invention is described solely in terms of a method of its making coupled with its function and there is no described or art-recognized correlation or relationship between the structure of the invention and its function. A biomolecule sequence described only by a functional characteristic, without any known or disclosed correlation between that function and the structure of the sequence, normally is not a sufficient identifying characteristic for written description purposes, even when accompanied by a method of obtaining the claimed sequence.

Given the failure of the specification to describe the claimed plant, methods of using it are also inadequately described. Accordingly, one skilled in the art would not have recognized Applicants to have been in possession of the claimed invention. See the written description guidelines published in Federal Register/ Vol. 66, No. 4/ Friday January 4, 2001/ Notices: pp. 1099-1111.

Enablement

9. Claims 1-6, 9-15 and 21 are rejected under 35 U.S.C. 112, first paragraph, as failing to comply with the enablement requirement. The claim(s) contains subject matter which was not described in the specification in such a way as to enable one skilled in the art to which it pertains, or with which it is most nearly connected, to make and/or use the invention. The claims are broadly drawn to any paprika plant and parts thereof characterized by certain morphological traits.

In re Wands, 858F.2d 731, 8 USPQ2d 1400 (Fed. Cir. 1988) lists eight considerations for determining whether or not undue experimentation would be necessary to practice an invention. These factors are: the quantity of experimentation necessary, the amount of direction or guidance presented, the presence or absence of working examples of the invention, the nature of the invention, the state of the prior art, the relative skill of those in the art, the predictability or unpredictability of the art, and the breadth of the claims.

Claims 1-3 and 9-12 are broadly drawn to any paprika plant and parts thereof having total carotenoids content higher than 10 mg/g dry fruit weight and a branching pattern suitable for mechanical harvesting, any paprika plant having fruit with a beta carotene content higher than 1.5 mg/g dry fruit weight, and any paprika plant having a branching angle not exceeding 40 degrees from main stem and branch points 30 cm above the ground, respectively.

The specification does not teach how to make and use the broadly claimed genus of paprika plants having the claimed characteristics. The specification only teaches the cultivars 1056 and 1057 having total carotenoids content higher than 10 mg/g dry fruit weight and fruit with a beta carotene content higher than 1.5 mg/g dry fruit weight (see page 14, Table 3); however the specification does not teach any paprika plant having a branching pattern suitable for mechanical harvesting nor does it teach any paprika plant having a branching angle not exceeding 40 degrees from main stem and branch points 30 cm above the ground. Thus, it would require undue

experimentation for one skilled in the art to make and use the invention as broadly claimed.

Claims 4-6 are broadly drawn to any paprika plant having an average height, fruits per plant, and dry fruit yield, respectively, greater than that of *Capsicum annuum* cv Lehava.

The specification does not teach how to make and use the broadly claimed genus of paprika plants having the claimed characteristics. The specification only teaches the cultivars 1056 and 1057 having an average height, fruits per plant, and dry fruit yield greater than that of *Capsicum annuum* cv Lehava (see page 12, Table 1). Thus, it would require undue experimentation for one skilled in the art to make and use the invention as broadly claimed.

Claims 13-15 are broadly drawn to any paprika plant having total carotenoids content higher than 10 mg/g dry fruit weight and a branching pattern suitable for mechanical harvesting, wherein the paprika plant has a height exceeding 90 cm, an average fruit length of at least 11 cm, an average fruit width of at least 2.9 cm, an average fruit dry weight of at least 3.5 g, an average number of fruits per plant at least 11.7 fruits, and an average fruit dry weight yield of at least 0.65 kg per m² and wherein said plant has brown or yellow seeds.

The specification does not teach how to make and use the broadly claimed genus of paprika plants having the claimed characteristics. The specification only teaches the cultivars 1056 and 1057 having total carotenoids content higher than 10 mg/g dry fruit weight and a branching pattern suitable for mechanical harvesting,

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wherein the paprika plant has a height exceeding 90 cm, an average fruit length of at least 11 cm, an average fruit width of at least 2.9 cm, an average fruit dry weight of at least 3.5 g, an average number of fruits per plant at least 11.7 fruits, and an average fruit dry weight yield of at least 0.65 kg per m² and wherein said plant has yellow seeds (see page 11, line 28; page 12, Table 1; and page 14, Table 3). The specification does not teach any paprika plants having the claimed characteristics and having brown seeds.

Claim 21 is broadly drawn to a system for developing a paprika plant using plant breeding techniques, wherein the system comprises the paprika plant cv 1056 or cv 1057.

There is no teaching in the specification of the genus of systems for developing a paprika plant using plant breeding techniques. The claims are broadly drawn to any "system" for developing paprika plants. The specification does not teach the broad genus of systems that are available to develop paprika plants. The specification only teaches a system comprising the crossing of Lehava with line 4126, the selection and self-fertilization of the resultant F1, and the use of pedigree breeding over the F2 to F6 generations (see page 11, lines 1-8).

Carotenoid content can vary and is dependent upon many factors. Hornero-Mendez et al (J. Agric. Food Chem.. 48: 3857-3864, 2000) teach, "The higher or lower carotenoid content for a given cultivar depends on various factors: greater or lesser expression of the genes governing carotenogenesis, physiological and morphological

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characteristics intrinsic to the cultivar, and growth conditions" (see page 3861, second column to page 3862, first column, line 1).

Given the breadth of the claims, the lack of guidance in the specification regarding the genus of paprika plants, and the many factors involved in carotenoid content, it would require undue experimentation for one of skill in the art to make and use the invention as claimed.

Lack of Deposit

10. Claims 4-8 and 19-21 are rejected under 35 U.S.C. 112, first paragraph, as failing to comply with the enablement requirement. The claim(s) contains subject matter which was not described in the specification in such a way as to enable one skilled in the art to which it pertains, or with which it is most nearly connected, to make and/or use the invention. The claims are drawn to a paprika plant of cv 1056 or cv 1057 and parts thereof characterized by certain morphological traits or to a paprika plant that is compared to cv Lehava.

Since the cv 1056, cv 1057 and Lehava paprika plants are essential to the claimed inventions, they must be obtainable by a repeatable method set forth in the specification or otherwise be readily available to the public. If the plants are not so obtainable or available, the requirements of 35 U.S.C. 112 may be satisfied by a deposit of the plant. The specification does not disclose a repeatable process to obtain the plant and it is not apparent if the plants are readily available to the public. Thus, a deposit is required for enablement purposes. A deposit of 2500 seed of each of the claimed embodiments is considered sufficient to ensure public availability. If the deposit is made

under the terms of the Budapest Treaty, then an affidavit or declaration by applicants, or a statement by an attorney of record over his or her signature and registration number, stating that the specific strain has been deposited under the Budapest Treaty and that the strain will be irrevocably and without restriction or condition released to the public upon the issuance of a patent, would satisfy the deposit requirement herein.

If the deposit has not been made under the Budapest Treaty, then in order to certify that the deposit meets the criteria set forth in 37 C.F.R. 1.801-1.809, applicants may provide assurance of compliance by an affidavit or declaration, or by a statement by an attorney of record over his or her signature and registration number, showing that

- (a) during the pendency of this application, access to the invention will be afforded to the Commissioner upon request;
- (b) all restrictions upon availability to the public will be irrevocably removed upon granting of the patent;
- (c) the deposit will be maintained in a public depository for a period of 30 years or 5 years after the last request or for the effective life of the patent, whichever is longer;
- (d) a test of the viability of the biological material at the time of deposit (see 37 C.F.R. 1.807) and,
- (e) the deposit will be replaced if it should ever become inviable.

Claim Rejections - 35 USC § 102

11. The following is a quotation of the appropriate paragraphs of 35 U.S.C. 102 that form the basis for the rejections under this section made in this Office action:

A person shall be entitled to a patent unless –

(b) the invention was patented or described in a printed publication in this or a foreign country or in public use or on sale in this country, more than one year prior to the date of application for patent in the United States.

12. Claims 1-6 and 9-15 are rejected under 35 U.S.C. 102(b) as being anticipated by Levy et al (J. Agric. Food Chem. 43: 362-366, 1995). The claims read on a paprika plant or its parts thereof having a total carotenoids content higher than 10 mg/g dry fruit weight and a branching pattern suitable for mechanical harvesting.

Levy et al teach paprika plants having a total carotenoids content higher than 10 mg/g dry fruit weight and a branching pattern suitable for mechanical harvesting (see page 364, Table 1 and page 362, second column, first paragraph, respectively). See *In re Best*, 195 USPQ 430, 433 (CCPA 1997), which teaches that where the prior art product seems to be identical to the claimed product, except that the prior art is silent as to a particularly claimed characteristic or property, then the burden shifts to Applicant to provide evidence that the prior art would neither anticipate nor render obvious the claimed invention.

Allowable Subject Matter

13. Claims 7 and 8 objected to as being dependent upon a rejected base claim, but would be allowable if rewritten in independent form including all of the limitations of the base claim and any intervening claims.

Conclusion

14. Claims 7-8 and 19-21 are deemed free of the prior art given the failure of the prior art to teach or suggest the paprika plant *Capsicum annuum* cv 1056 or 1057, or using said plants as a source of breeding material.

15. Claims 1-6, 9-15, and 19-21 are rejected.

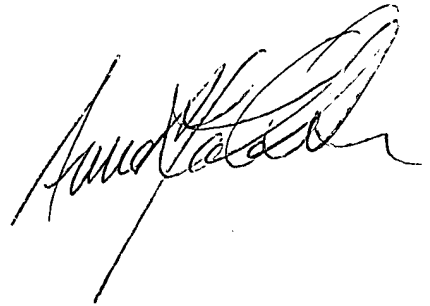
16. Any inquiry concerning this communication or earlier communications from the examiner should be directed to Keith O. Robinson, Ph.D. whose telephone number is 571-272-2918. The examiner can normally be reached on Monday - Friday 7:30 am - 4:00 pm.

If attempts to reach the examiner by telephone are unsuccessful, the examiner's supervisor, Amy Nelson, Ph.D. can be reached on 571-272-0804. The fax phone number for the organization where this application or proceeding is assigned is 571-273-8300.

15. Information regarding the status of an application may be obtained from the Patent Application Information Retrieval (PAIR) system. Status information for published applications may be obtained from either Private PAIR or Public PAIR. Status information for unpublished applications is available through Private PAIR only. For more information about the PAIR system, see <http://pair-direct.uspto.gov>. Should you have questions on access to the Private PAIR system, contact the Electronic Business Center (EBC) at 866-217-9197 (toll-free).

Keith O. Robinson, Ph.D.

May 17, 2005

A handwritten signature in black ink, appearing to read 'Anne Kubelik', with a long, sweeping horizontal line extending from the bottom of the signature.

**ANNE KUBELIK, PH.D.
PRIMARY EXAMINER**